REMARKS

This communication is in response to the final Office Action mailed October 31, 2006. Applicants have amended claims 1 and 77. Claims 54 and 55 have been canceled. Claims 116 and 117 stand allowed. Support for the amendments may be found throughout the specification and claims as originally filed. The above amendments are not to be construed as acquiescence to the Examiner's stated grounds for rejections and are made without prejudice to prosecution of any subject matter removed or modified by this amendment in a related divisional, continuation or continuation-in-part application. Favorable reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 1-28, 49-62, 77 and 103-109 stand newly rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite due to use of the phrase "repeat region within SEQ ID NO:1." More particularly, it is allegedly unclear what sequences represent the repeat region and where the antibody or fragment is binding.

Without acquiescing to the stated grounds for rejection, the phrase alleged by the Examiner to be indefinite has been removed from the pending claims. Withdrawal of this rejection is requested.

Rejection Under 35 U.S.C. §112, First Paragraph

Claims 1-28, 49-62, 77 and 103-109 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. According to the Examiner, the specification discloses three repeat regions within amino acids 14-452 of Figure 1, and SEQ ID NO:1, but does not disclose any other repeat regions as broadly encompassed in the claims.

Claim 1 has been amended, for purposes of clarity and to advance prosecution, to recite that the claimed antibody, or antigen-binding antibody fragment, binds to the amino acid sequence from residues 14-452 of SEQ ID NO:1, wherein the antibody preferentially binds cell-associated CA 125/O772P polypeptide relative to shed CA 125/O772P polypeptide.

The specification describes, in reference to Figure 1, that the: "(i)talicized residues from amino acid 14 to amino acid 452 represent repeat regions. Each of the three repeats within the 14-452 repeat region are delineated by vertical lines and arrows as shown." (page 22, lines 85-87). Thus, from the specification, it is clear that "the repeat region present within SEQ ID NO:1" corresponds to amino acid residues 14-452 of SEQ ID NO:1.

In this respect, Applicants note that an important inventive contribution made by the present disclosure stems from the identification of this particular region as being part of a CA 125/O772P polypeptide that retains an association with the cell surface following release of the shed form of CA125/O772P. This region, referred to in the specification as the "repeat region" and being defined as amino acid residues 14-452 of SEQ ID NO:1, can be used according to the present invention in generating antibodies that preferentially bind to cell-associated CA125/O772P. This is particularly important, for example, in the context of developing antibody-based diagnostic and/or therapeutic agents for targeting the cancer cells that express CA125/O772P, since this region retains an association with the cell surface even after the shed form of CA125/O772P is released.

Thus, it is important in the context of the present invention that antibodies bind to the sequences claimed, from amino acid residues 14-452 of SEQ ID NO:1, and in doing so preferentially bind cell-associated CA 125/O772P polypeptide relative to shed CA 125/O772P. What is not important in this respect is the particular delineation of the 3 repeats within the claimed region or precisely where within the region a given antibody binds. An artisan of ordinary skill would understand, in view of the present disclosure, that antibodies that binds to the amino acid sequence from residues 14-452 of SEQ ID NO:1, as claimed, can preferentially binds cell-associated CA 125/O772P polypeptide relative to shed CA 125/O772P polypeptide, since this region is retained even after the shed form of CA 125/O772P polypeptide is released.

Under the Examination Guidelines set forth by the Patent and Trademark Office, the written description requirement for a claimed genus may be satisfied by the description of a representative number of species or the disclosure of relevant, identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. Guidelines for Examination of Patent Applications under the 35 U.S.C. § 112, ¶1, "Written Description"

Requirement, 66 Fed. Reg. 1099, at 1106 (emphasis added). Examples of such identifying characteristics include complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, etc. (*e.g.*, at 1106). In addition, for biomolecules, illustrative identifying characteristics may include a sequence, structure binding affinity, *binding specificity*, molecular weight, etc. (*e.g.*, at 1110).

The present application more than adequately satisfies these requirements. First, Applicants have generated and characterized a large number of representative antibodies, as described in the Examples, which are specific for the amino acid sequence from residues 14-452 of SEQ ID NO:1, and which preferentially binds cell-associated CA 125/O772P polypeptide relative to shed CA 125/O772P polypeptide, as claimed. Further, the specification and claims provide distinguishing identifying characteristics that are common to the claimed genus of antibodies and that further evidence possession of the claimed genus. The claims recite the specific structure of the amino acids sequence to which the claimed antibodies bind, i.e., amino acid residues 14-152 of SEQ ID NO:1, and further recite the binding specificity of the claimed antibodies, i.e., that they preferentially bind cell-associated CA125/O772P relative to shed CA125/O772P. Thus, the claims recite structural features coupled with functional binding specificity requirements. Reconsideration of the Examiner's rejection is requested.

Claims 54 and 55 remain rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement.

In an effort to advance prosecution, but without prejudice to further prosecution of this subject matter in a related application, claims 54 and 55 have been canceled.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Favorable reconsideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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